भारतीय मानक
Indian Standard

IS 17588 : 2021

कोल्ड बॉक्स के लिए विशिष्टि — सामान्य अपेक्षाऐं एवं परीक्षण विधियाँ

Specification for Cold Box — General Requirements and Test Methods

ICS 11.040.01

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November 2021 **Price Group 6**

Hospital Equipment and Surgical Disposable Sectional Committee, MHD 12

FOREWORD

This Indian Standard was adopted by Bureau of Indian Standards after the draft finalized by the Hospital Equipment and Surgical Disposable Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This Indian Standard specifies the essential requirements for thermally insulated cold boxes which are used to collect and transport vaccine supplies from one fixed vaccine store to another and from vaccine stores to health facilities.

In preparation of this standard, assistance has been drawn from specifications received from Technical Specifications Development Group (TSDG) for Cold Chain Equipment, National Cold Chain and Vaccine Management Resource Centre (NCCVMRC), Department of Health and Family Welfare.

The composition of the Committee responsible for the formulation of this standard is given in Annex E.

In reporting the result of a test or analysis made in accordance with this standard, if the final value, observed or calculated, is to be rounded off, it shall be done in accordance with IS 2 : 1960 ‘Rules for rounding off numerical values (*revised*)’.

Indian Standard

SPECIFICATION FOR COLD BOX — GENERAL REQUIREMENTS AND TEST METHODS

1 SCOPE

This Indian Standard specifies the essential requirements for thermally insulated cold boxes which are used to collect and transport vaccine supplies from one fixed vaccine store to another and from vaccine stores to health facilities. This standard covers both short range and long range cold boxes.

2 REFERENCE

The standards listed below contain provisions which, through reference in this text, constitute provision of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreement based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated:

IS No./Other Publications	*Title*
IS/IEC 60529 : 2001	Degrees of protection provided by enclosures (IP CODE)
ISO 20282-1 : 2006	Ease of operation of everyday products — Part 1: Context of use and user characteristics
IS 17589 : 2021	Specification for water packs for use as ice-packs, cool-packs and warm-packs— Requirements and test methods (*under print*)

3 TERMS AND DEFINITIONS

For the purposes of this standard, the following terms and definitions apply.

3.1 Cold Boxes — Cold boxes are insulated containers that can be lined with water packs are for short duration storage of pre-cooled vaccine and its transportation from one fixed vaccine store to another, within the specified temperature range.

3.2 Short Range Cold Box — Cold boxes with a minimum cold life of 48 h that can be used for transportation/storage for only a short period of time.

3.3 Long-range Cold Box — Cold boxes with a minimum cold life of 96 h that can be used for transportation/storage for a longer period of time.

3.4 Cold Life — When the empty container is stabilized at +43 °C, loaded with frozen icepacks and the lid closed, the time taken for the temperature of the warmest point in the vaccine storage compartment to first reach +10°C, at a constant ambient temperature of +43 °C.

NOTE — The "cold life" of a cold box is the maximum length of time that a closed cold box can maintain temperatures below +10 °C when it is lined with frozen ice packs at a constant ambient temperature of +43 °C.

3.5 Cool Life — When the empty container is stabilized at +43 °C and loaded with cool-packs which have been stabilized at + 5 °C for a minimum of 24 h and the lid closed, the time taken for the temperature of the warmest point in the vaccine storage compartment to first reach +20 °C, at a constant ambient temperature of +43 °C is called Cool life.

NOTE — The "cool life" of a cold box is the maximum length of time the closed cold box can maintain temperatures below +120 °C if lined with cool water packs that have been stored in a refrigerator at a constant ambient temperature of +43 °C.

3.6 Warm Life — When the empty container is stabilized at +18 °C and loaded with warm-packs which have been stabilized at the same temperature for a minimum of 24 h and the lid closed, the time taken for the temperature of the coldest point inside the vaccine storage compartment first reaches 0 °C at a constant ambient temperature of –20 °C is called warm life.

3.7 Ice-pack — A water-pack frozen to a temperature between –5 °C and –20 °C before use is called icepack.

NOTE — Ice-packs are used frozen for the transport of oral polio vaccine (OPV), and used conditioned for the transport of all other freeze sensitive vaccines.

3.8 Cool-pack — A water-pack pre-cooled to a temperature between + 2 °C to + 8 °C before use is called cool-pack.

3.9 Water-pack — A flat, leak proof, plastic container, filled with tap water. It is a robust container designed to store water which, when frozen, cooled or warmed to an appropriate temperature, provides the thermal inertia needed to maintain safe storage conditions for vaccines and biological specimens when carried inside a cold box or vaccine carrier.

3.10 Warm-pack — A water-pack typically stabilized at room temperature, up to a recommended maximum of + 24 °C. Warm-packs are used for the transport of freeze sensitive vaccines in places where sub-zero temperatures are common.

3.11 Phase Change Material (PCM) — A material, other than water, which changes state between solid and liquid or changes between two different solid crystallization states over a defined temperature range, absorbing or releasing heat during the phase change. This process is reversible and can be useful for thermal control in cold chain devices and products.

3.12 Vaccine Storage Capacity — The total volume of the vaccine storage compartment, in liters. The measurement is equal to the volume of the largest rectilinear object that can be inserted into the compartment with all the manufacturer's specified packs in place.

3.13 Vaccine Storage Compartment — The zone within an insulated container which is designated by the manufacturer as suitable for storing vaccine when the container is loaded with the full number of water-packs required to achieve the cold life specified in this standard.

4 REQUIREMENTS

4.1 General

Short range or long range insulated cold box, with hinged and insulated lid, designed for transporting vaccines.

4.2 Performance

4.2.1 *Vaccine Storage Capacity*

a) Short range : 5.0 to 14.0 liters.
b) Long range : 15.0 to 25.0 liters.

4.2.2 *Cold Life*

a) Short range : minimum 48 h.
b) Long range : minimum 96 h.

4.2.3 *Shape*

Cold boxes shall be substantially square or rectangular in plan and section. Rounded corners are preferred.

4.2.4 *Design Principles*

The design of the container, including the placement of the packs and of the load, shall promote the free circulation of air within the container to ensure minimum temperature stratification. The product shall be designed in accordance with the general usability principles laid out in ISO 20282-1 : 2006. All types of cold boxes shall be designed so that they can comfortably be carried, when fully loaded.

4.2.5 *Lid Seal*

The lid of the container must be fitted with a captive labyrinth seal which engages with the container walls when the lid is closed so as to minimize cold bridging and maximize structural strength.

4.2.6 *Hinges*

The lid of the container shall be fitted with a robustly constructed hinge mechanism. The lid must open beyond 90° to give full access to the interior of the cold box. The hinges shall be recessed so that they are fully protected against damage during transport and storage. Hinges shall be maintenance free, without need for lubrication and must be secured to the container in a manner which prevents loosening due to vibration.

4.2.7 *Lid Stay*

The container shall be fitted with a stay device designed to prevent damage caused by over-stressing the lid when open. The stay device shall be designed to prevent it becoming trapped between the lid seal and the body of the container when the lid is closed and it shall be secured to the container in a manner which prevents loosening due to vibration.

4.2.8 *Catches*

The lid of the container shall be secured in the closed position by a catch or catches and it must not be possible for a catch to open accidentally once engaged. Catches shall be recessed so that they are fully protected against damage during transport and storage. Catches shall be maintenance-free, without need for lubrication and shall be secured to the container in a manner which prevents loosening due to vibration.

4.2.9 *Carrying Handles*

The body of the container shall be fitted with at least two molded-in or hinged handles designed so that they can be used to lift and carry the container comfortably when it is fully loaded. Hinge mechanisms shall restrain the handle in a near-horizontal position when the container is lifted and the handles shall automatically drop back into the vertical position when they are released. Preferably the handles should be recessed so that they are fully protected against damage during transport and storage. Handles shall be maintenance-free, without need for lubrication and must be secured to the container in a manner which prevents loosening due to vibration. The handle arrangement shall not prevent stable stacking of the boxes.

4.2.10 *Vaccine Storage Advice*

Cold boxes shall carry factory-fitted non-removable labels designed to last the lifetime of the cold box.

Labels should be in the language to the country of use (that is, English, or other language, by special order) and should carry the following information:

a) On the outside of the lid, and/or on the front face of the cold box as provided in Annex A; and
b) On the inside of the lid as provided in Annex B.

4.2.11 *Stacking and Handling*

The design of the base and lid of the container should include molded features that allow multiple units of the same model to be stacked on top of one another in a safe and stable manner. The base of the container shall be designed to withstand repeated dragging across hard rough floor surfaces**.**

4.2.12 *Corrosion Resistance*

All metallic components and their fixings shall be constructed in stainless steel or a suitable non-ferrous metal.

4.2.13 *Chemical Resistance*

The external and internal surfaces of the container shall be resistant to chemicals used for disinfecting (for example, sodium hypo chlorate, 5.25 percent in water).

4.2.14 *Ingress Protection Rating*

Protection of the container with lid closed and latched not less than IEC 60529 : IP55.

4.2.15 *Robustness*

The container shall withstand a one meter drop on to each face, edge, and corner at its rated fully-loaded weight. At the end of the test there shall be no damage that affects the performance of the product and the lid shall still be closed and latched properly.

4.3 Environmental Requirements

4.3.1 *Ambient Temperature Range*

The ambient temperature range during transport, storage and use of the cold boxes should be from – 30 °C to + 55 °C.

4.3.2 *Humidity Range*

The ambient humidity range during transport, storage and use of the cold boxes should be from 5 percent to 95 percent RH.

4.4 Physical Characteristics

4.4.1 *Overall Dimensions*

In conformity with **4.5.1** to **4.5.3**.

4.4.1 *Weight*

The weight of the container must not exceed the following figures:

a) Short range: Maximum loaded weight, inclusive of the recommended number of water filled water-packs 35.0 kg.
b) Long range: Maximum loaded weight, inclusive of the recommended number of water filled water-packs 50.0 kg.

4.5 Interface Requirements

4.5.1 *Dimensional Compatibility with Packs*

The internal dimensions of the container shall be compatible with any of the three standard types of water-pack. However, it is acceptable for the product to achieve its designated cold life at its designated vaccine storage capacity using only one of these three types.

4.5.2 *Dimensional Compatibility with Vaccine Packaging*

Cold boxes are generally used to transport vaccine in secondary packaging. The net dimensions of the storage compartment (length, breadth and height, with water-packs in place) should accommodate the widest possible range of standard immunization vaccines in this form of packaging, with the vials arranged upright in the container as given in Table 1.

Table 1 Dimensions of the Storage Compartment

(*Clause* 4.5.2)

	Length (cm)	Breadth (cm)	Height (cm)
Maximum	25.3	16.4	14.5
Minimum	6.1	2.9	1.7
95th Percentile	19.5	14.8	11.0

4.5.3 *Dimensional Compatibility with Transport Mode*

a) Short-range cold boxes shall be designed so that they can safely be carried upright inside cars, light vans or 4WD vehicles, strapped to the luggage rack of a small motorcycle or moped or carried by a single porter or a pack animal.
b) Long-range cold boxes shall be designed so that they can safely be carried upright inside cars, light vans, 4WD vehicles or boats, or carried by two porters or a pack animal.

4.5 Human Factors

The product shall be designed in accordance with the general usability principles laid out in ISO 20282-1 : 2006.

4.6 Materials

4.6.1 *Casing Material Selection*

Internal and external casing materials shall resist UV degradation and all joints between the molded components shall be water and vapor proof, shall be easy to clean and shall be selected with environmentally safe end-of-life disposal in mind. Chlorinated plastics and composites containing epoxy resins shall not be used.

4.6.2 *Thermal Insulation Foaming Agents*

Any gas complying with the limitations and deadlines set by the montreal protocol on the elimination of ozone-depleting chemicals. Cyclopentane and similar foaming agents with a low global warming potential (GWP) are preferred.

4.6.3 *Other Restricted Materials*

The product and its constituent components shall not contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated biphenyl ethers (PBDE).

5 TEST METHODS

Number of samples : Two samples of the product are required, together with empty water-packs, conforming to **MHD 12 (13695)**. The quantity of water-packs supplied must equal the number of packs recommended by the container manufacturer plus sufficient additional packs to fill an empty container entirely, in accordance with the requirements of Robustness Test and to provide spares in the event of leakage or other eventuality.

The S/N of all the Testing equipment and instruments should be listed in the test report along with the calibration status of the equipment and instruments used in testing.

5.1 Robustness Test (To be done with Sample 1)

5.1.1 *Test Conditions*

a) Test chamber at + 18.0 °C to + 24.0 °C and ambient humidity. Record conditions at time of test.

b) Line the perimeter of the container with filled water-packs in accordance with the container manufacturer's instructions. Fully fill the central void with a non-breakable dummy load and suitable soft packaging arranged to prevent the load from shifting during the clause 5.1.4 drop test. The total weight of the water-pack lining and the dummy load shall equal the maximum loaded weight established in **5.2**.

NOTE — Water-packs, gel-packs or sand bags may be used as a dummy load.

c) Mark the faces, edges and corners of the container with the test numbers shown in the Table 2 to **5.1.1 (d)**.

d) Using a free fall drop tester, drop the container 26 times from a height of one meter (measured from the lowest part of the container at the start of each test) onto a smooth dense concrete floor in the exact order set out in the following table. Cancel the relevant test number marking after each drop so as to avoid inadvertent duplication.

Table 2 Faces, Edges and Corners for the Drop Test

(*Clause* 5.1.1)

Face	Edges	Corners
1 Top	7 Front top	19 Front top left
2 Bottom	8 Back top	20 Front top right
3 Front	9 Left side top	21 Back top left
4 Back	10 Right side top	22 Back top right
5 Left side	11 Front bottom	23 Front bottom left
6 Right side	12 Back bottom	24 Front bottom right
13 Left side bottom		25 Back bottom left
14 Right side bottom		26 Back bottom right
15 Front left side		
16 Front right side		
17 Back left side		
18 Back right side		

e) Stop the test after the 26th drop or when part of the load falls out, whichever is the sooner. If the load falls out prematurely due to failure of the hinges and/or catches, re-secure the lid and continue the test.

f) After each drop note any damage that has occurred. Assess the overall damage at the end of the test according to the ratings given in Table 3.

Table 3 Damage Ratings

(*Clauses* 5.1.1 *and* 5.1.2)

Rating	Damage to Casing	Rating	Damage to Fittings
1	Heavy damage or lid pulled off	1	Hinges and/or catches and/or handles broken
2	Easily repairable damage	2	Hinges and/or catches become undone and/or handles distorted.
3	Superficial damage	3	Hinges, catches and handles function correctly.
4	Slightly marked		
5	Unmarked		

5.1.2 *Acceptance Criteria*

The acceptable Rating for both the Casing and the fitting tests are Casing-2, Fitting-2 as shown in Table 3. Results will be reported.

5.1.3 *Rejection Criteria*

Failure to achieve rating 2 or above for either or both of the casing and fittings tests.

5.2 Test for Dimensions, Weights and Vaccine Storage Capacity

5.2.1 *Test Conditions*

a) Test chamber between +18.0 °C and +24.0 °C at ambient humidity. Record conditions at the time of the test.

b) Record maximum external dimensions in centimeters (length, width and height, with handle folded, (± 0.5 cm)).

c) Record minimum internal dimensions in centimeters, without water-packs (length, width and height, (± 0.5 cm)).

d) Record the empty weight of the container, without water-packs, in kilograms (± 0.1 kg). Take the number of water-packs designated by the container manufacturer. The total volume of water in the set of water-packs shall equal the following formula:

(water-pack manufacturer's rated water volume) × **(designated no. of waterparks) (± 2.0 percent).**

e) Fill each water-pack in the set with the equal volumes of tap water, stabilize data temperature of +20.0 °C (±2.0 °C). Record the total volume of water used and the total weight of the filled water-packs.

f) Fully freeze the set of water-packs at –20.0 ºC (±2.0 ºC). Line the container with the ice-packs in accordance with the manufacturer's instructions. Record the minimum overall dimensions of the vaccine storage compartment measured between straight edges placed over the bulging internal faces of the ice-packs (length, width and height, (± 0.5 cm)).

g) Weigh the cold box, in kg, with the ice-packs in place. Pack the vaccine storage compartment up to the manufacturer's designated load line with the maximum possible number of cardboard boxes or blocks made out of plastic foam or wood, measuring 100 × 100 × 100 mm and 100 × 100 × 50 mm. Ensure that the lid of the container can be closed and latched. Measure the total volume of the test units in liters and multiply by 0.55 kg. Add this figure to the measured empty weight. Record the total weight in kilograms (5 ± 0.1 kg) as the maximum loaded weight. Record the total volume of the boxes as the vaccine storage capacity.

NOTE — Place a layer of ice-packs above the load if this is shown on the manufacturer's loading diagram. Include these when measuring the empty weight.

5.2.2 *Acceptance Criteria*

The container should conform to the volumetric ranges and weight limits set out in the Table 4.

Table 4 Volumetric Range and Weight Limits

(*Clause* 5.2.2)

Type	Vaccine Storage Capacity (L)	Maximum Loaded Weight (kg)
Short range	5 to 14 liter	35 kg
Long range	15 to 25 liter	50 kg

5.2.3 *Rejection Criteria*

Maximum empty weight or maximum loaded weight outside designated ranges. Vaccine storage capacity below the minimum designated volume. If the vaccine storage capacity exceeds the designated maximum, but empty and loaded weights remain within the designated upper limits, the container can be accepted, but results will be reported.

5.3 Cold Life Test (To be Carried out with Sample 2)

5.3.1 *Test Conditions*

a) Test chamber at +43.0 °C (± 0.5 °C).

b) Stabilize the container in the +43 °C test chamber for a minimum of 24 h, with the lid open.

c) Assemble a dummy vaccine load comprising partially filled waterparks with a combined density of 0.4 kg per liter of the measured vaccine storage capacity. The water-packs should be arranged so that they substantially fill the vaccine storage compartment, leaving voids for the sensor positions shown in Annex C. Condition the load in a refrigerator at + 5.0 °C (±0.5 °C).

d) Fully freeze the set of water-packs as described in **5.2** at –20.0 ºC (±0.5 °C). Line the container with the ice-packs in accordance with the manufacturer's instructions. Place the conditioned load in the vaccine storage compartment together with the Annex D temperature sensors laid out as shown in the Annex C diagram. Ensure that the sensors do not touch the adjacent water-packs. Close the lid of the cold box.

e) Monitor temperatures at one minute intervals until the temperature of the warmest point in the vaccine load first reaches +10.0 ºC. Record the temperature of the coldest point in the load at this time. The cold life is measured from the moment when the container lid is closed until the temperature of the warmest point in the vaccine storage compartment first reaches + 10 °C.

5.3.2 *Acceptance Criterion*

The cold-life must be a minimum of 48 h for short range containers and a minimum of 96 h for long range containers.

5.3.3 *Rejection Criterion*

Failure to achieve the minimum cold life.

5.4 Cool Life Test (Optional)

5.4.1 *Test Conditions*

a) Test chamber at + 43.0 °C (± 0.5 °C).

b) Stabilize the container in the + 43 °C test chamber for a minimum of 24 h, with the lid open.

c) Reuse the dummy vaccine load described in test **5.3**, Step **5.3.3**. Condition the load in a refrigerator at + 5.0 °C (± 0.5 °C).

d) Stabilize the set of water-packs described in test **5.2**, step **5.2.5** at +5.0 ºC (± 0.5 °C). Line the container with the cool-packs in accordance with the manufacturer's instructions. Place the conditioned load in the vaccine storage compartment together with the Annex B temperature sensors laid out as shown in the Annex A diagram. Ensure that the sensors do not touch the adjacent water-packs. Close the lid of the cold box.

e) Monitor temperatures at one minute intervals until the temperature of the warmest point in the vaccine load first reaches + 20.0 ºC. Record the temperature of the coldest point in the load at this time. The cool-life is defined as the time interval from the moment when the lid is closed until the temperature of the warmest point first reaches + 20.0 ºC.

5.4.2 *Acceptance Criterion*

There is no standard criterion for the acceptance. However, the results of the test may be reported as agreed between manufacturer and user.

5.5 Warm Life Test (Optional)

5.5.1 *Test Conditions*

a) Test chambers at –20.0 (±0.5 °C) and + 18.0 °C (± 0.5 °C).

b) Stabilize the container in the + 18 °C test chamber for a minimum of 24 h, with the lid open.

c) Reuse the dummy vaccine load described in test **5.3**, Step 5.3.3 Condition the load in a refrigerator at + 5.0 °C (± 0.5 °C).

d) Stabilize the set of water-packs described in test 5.2, Step 5.2.5 at +18.0 ºC (±0.5 °C). Line the container with the warm-packs in accordance with the manufacturer's instructions. Place the conditioned load in the vaccine storage compartment together with the Annex D temperature sensors laid out as shown in the Annex C diagram. Ensure that the sensors do not touch the adjacent water-packs. Close the lid of the cold box.

e) Place the loaded cold box in the –20 °C test chamber.

f) Monitor temperatures at one minute intervals until the temperature of the coldest point in the vaccine load first reaches 0.0 ºC. Record the temperature of the warmest point in the load at this time. The warm-life is defined as the time interval from the moment when the lid is closed until the temperature of the coldest point first reaches 0.0 ºC.

5.5.2 *Acceptance Criterion*

There is no standard criterion for the acceptance. However, the results of the test may be reported as agreed between manufacturer and user.

5.6 IP Rating Test to IS/lEC 60529

5.6.1 *Test Conditions*

a) Use sample 2, if IP test is required.

b) Obtain an independent test report from the manufacturer showing full conformity with IS/IEC 60529 : IP55. Only if this is not available.

c) Carry out an IP55 test on a single sample. Record results.

5.6.2 *Acceptance Criterion*

IP55 test passed.

5.6.3 *Rejection Criterion*

IP55 test failed.

5.7 Lining Integrity Test and Section through Reference Sample

5.7.1 *Test Conditions*

a) **Sample:** Sample 2 after completion of all other tests. Results of this test will be kept on file as a record of the reference sample in the event of future quality related issues arising in the field.

b) Fill the cold box with water to the top of the lining. Leave for two hours.

c) Empty the cold box and thoroughly dry the interior with tissue paper and/or warm air without applying pressure to the inner lining.

d) Apply firm hand pressure to the inner lining. Check for evidence of moisture extruded through pinholes in the lining.

e) Cut the sample in half laterally and vertically, including the lid. Cut one of the two halves at 45 degrees and vertically through the bottom corner of the container and through the corner of the lid.

f) Examine the construction closely. Photograph and record the following:

    1) The presence of voids in the insulated core;

    2) Evidence of moisture penetration through the inner lining; and

    3) Measure the thickness of the inner and outer casing at key points, including flat areas and corners (± 0.1 mm). Note any weak points in the moldings and sudden changes of thickness.

5.7.2 *Acceptance Criterion*

No significant voids in insulated core. No weak points in the moldings.

5.7.3 *Rejection Criterion*

Water penetration though inner lining. Insulation voids or molding weaknesses that adversely affect thermal performance or long-term robustness.

6 ACCOMPANYING DOCUMENTS

The accompanying documents shall include the following:

a) Instructions for use; and

b) Instructions for maintenance, cleaning and disinfection.

7 PACKING, MARKING AND LABELLING

7.1 Materials used for packaging the finished product are to be free of ozone depleting compounds as defined in the montreal protocol. The general specification of shipping containers shall be as agreed between manufacturer and purchaser.

7.2 The following shall be clearly and permanently marked on the container:

a) The manufacturer's name or trade-mark;

b) Shall be marked with the Indian Standard applicable;

c) The model (or commercial designation);

d) Serial number; and

e) Date of Manufacture.

7.3 Disposal and Recycling

The manufacturer is to provide information to the buyer on any hazardous materials contained within the product and suggestions for resource recovery/recycling and/or environmentally safe disposal.

7.4 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

ANNEX A

(*Clauses* 4.2.10 *and* 5.4.1)

LABEL ON OUTSIDE OF THE LID, AND/OR FRONT FACE OF COLD BOX

White lettering on red ground.

Black and white EPI logo

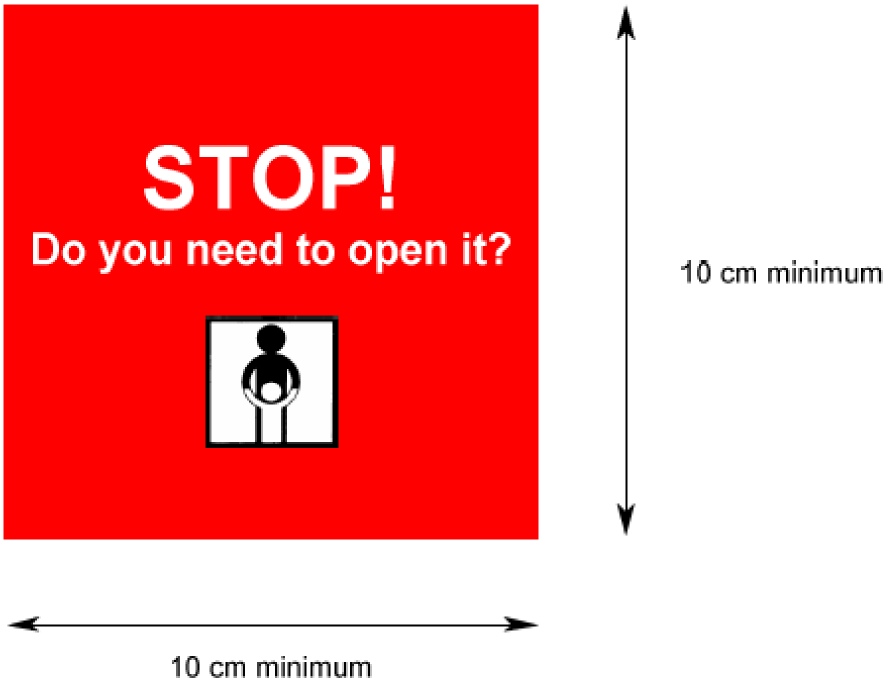
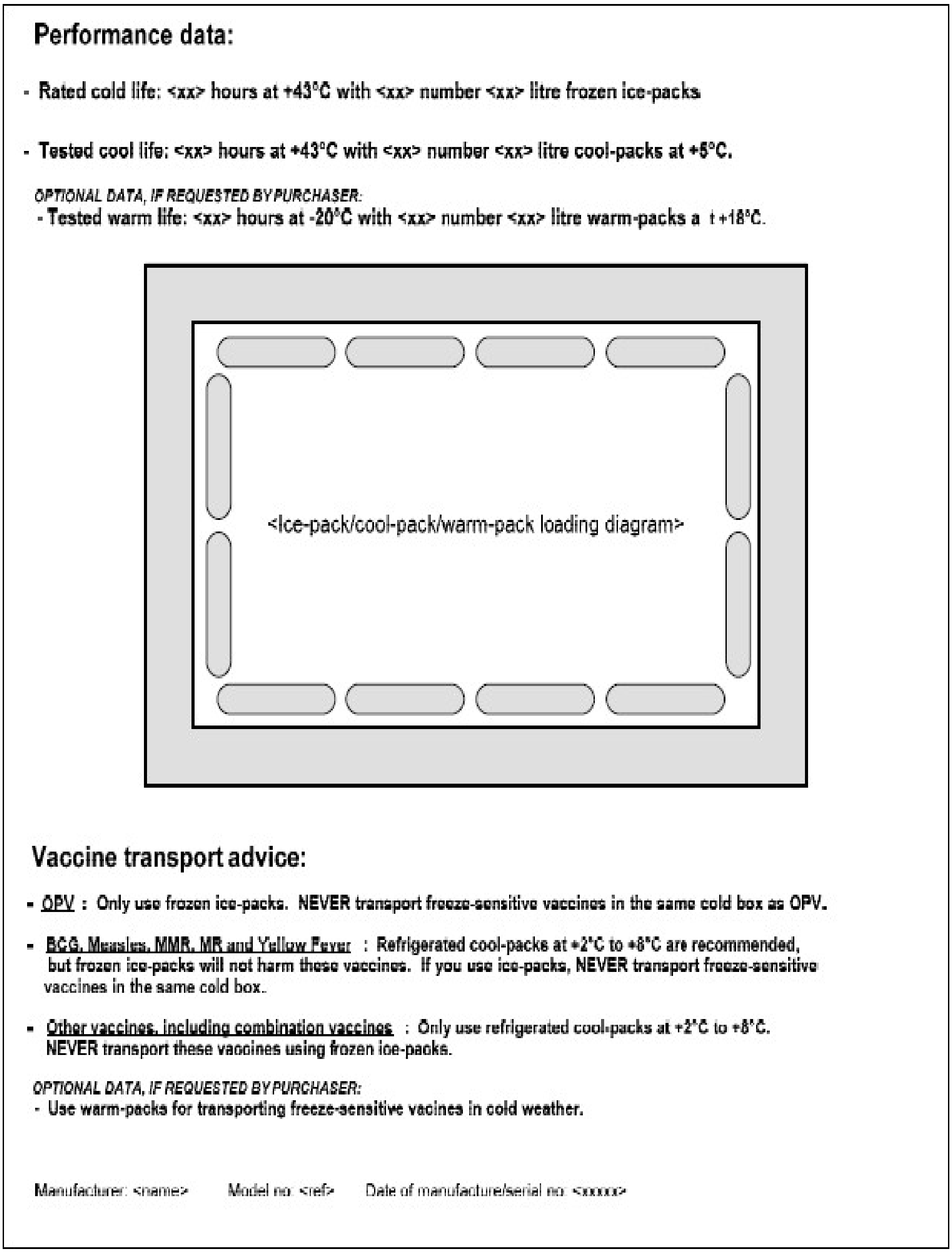


FIG. 1 LABEL ON OUTSIDE OF THE LID, AND/OR FRONT FACE OF COLD BOX

ANNEX B

(*Clauses* 4.2.10 *and* 5.4.1)

LABEL ON INSIDE OF LID



Performance data:

- Rated cold life: <xx> hours at +43°C with <xx> number <xx> litre frozen ice-packs
- Tested cool life: <xx> hours at +43°C with <xx> number <xx> litre cool-packs at +5°C.

OPTIONAL DATA, IF REQUESTED BY PURCHASER:

- Tested warm life: <xx> hours at -20°C with <xx> number <xx> litre warm-packs a t +18°C.

<Ice-pack/cool-pack/warm-pack loading diagram>

Vaccine transport advice:

- OPV : Only use frozen ice-packs. NEVER transport freeze-sensitive vaccines in the same cold box as OPV.
- BCG, Measles, MMR, MR and Yellow Fever : Refrigerated cool-packs at +2°C to +8°C are recommended, but frozen ice-packs will not harm these vaccines. If you use ice-packs, NEVER transport freeze-sensitive vaccines in the same cold box.
- Other vaccines, including combination vaccines : Only use refrigerated cool-packs at +2°C to +8°C. NEVER transport these vaccines using frozen ice-packs.

OPTIONAL DATA, IF REQUESTED BY PURCHASER:

- Use warm-packs for transporting freeze-sensitive vacines in cold weather.

Manufacturer: <name> Model no: <ref> Date of manufacture/serial no: <xxxxx>

FIG. 2 LABEL ON INSIDE OF THE LID

ANNEX C

(*Clause* 5.3.1)

TEMPERATURE SENSOR POSITIONS

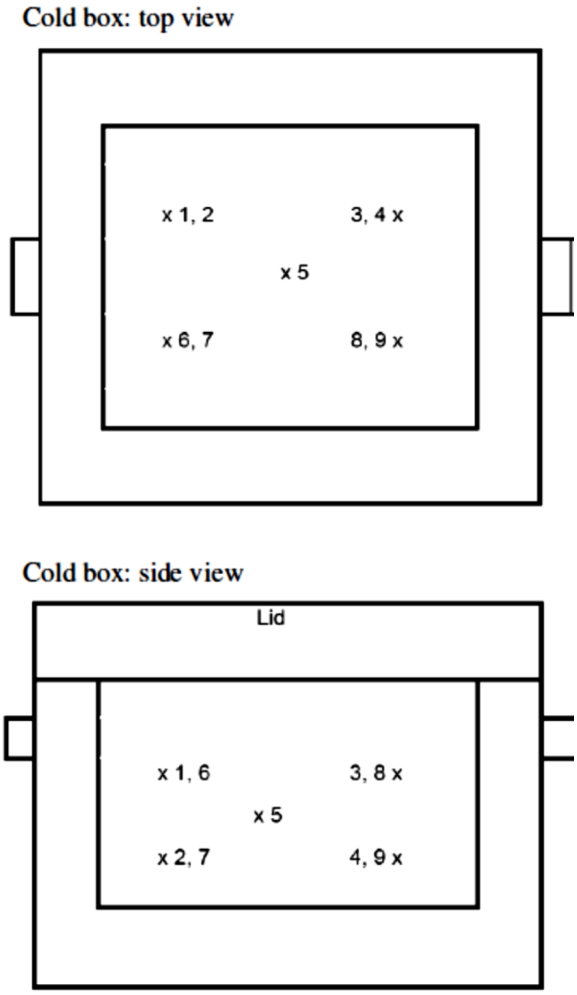


FIG. 3 POSITION OF THE TEMPERATURE SENSORS

NOTES

1 All measuring points, with the exception of the center one, must be 25-30 mm from the nearest ice-pack. Ensure that this is achieved using suitable fixing devices attached to the dummy load. Ensure that the load cannot rotate, or otherwise become displaced once the sensors are in place.

2 Sensor leads can be introduced into the container using one of two methods:

a) Through the lid seal, taking care not to affect the quality of the seal.
b) Through a hole in the geometric center of the lid, taking care to seal the outer and inner openings adequately.

ANNEX D

(*Clause* 5.3.1)

TEMPERATURE SENSOR SPECIFICATION

A standard temperature sensor probe, accurate to ± 0.5 °C, inserted into brass or tin-covered copper mass of 25 g ± 5 percent and of minimum external area (diameter = height = about 15.2 mm).

ANNEX E

(*Foreword*)

COMMITTEE COMPOSITION

Hospital Equipment and Surgical Disposable Sectional Committee, MHD 12

Organization	*Representative(s)*
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